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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/664,601

09/18/2003

Weenna Bucay-Couto

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07/27/2006

MAYER & WILLIAMS PC
251 NORTH AVENUE WEST
2ND FLOOR
WESTFIELD, NJ 07090

EXAMINER

BETTON, TIMOTHY E

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 07/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/664,601	Applicant(s) BUCAY-COUTO ET AL.	
	Examiner Timothy E. Betton	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-36 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-29, 33-36 drawn to a dosage form and method of forming said dosage form, classified, for example when the dosage form is an insertable or injectable chemical ablation agent with a biodisintegrable binder in class 424, subclass 9.2, 1.25, 1.33, 9.411, 422, 428, and 489. If this Group is elected then the below summarized species election is also required.

Group II. Claims 27 – 29 drawn to a method of forming the dosage, classified, for example when the dosage form is said ablation agent and said biodisintegrable binder in class 424, subclass 9.2. If this Group is elected then the below summarized species election is also required.

Group III. Claims 22 – 26 and 30- 32 drawn to a method of treatment, classified, for example when a treatment comprised of inserting, injecting transcutaneously, or transrectally via jet injection in class 424, subclass 422 and 9.6. If this Group is elected then the below summarized species election is also required.

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the process can be used with a mixture of these components, which are not injectable, or a mixture of these components, which are not sterile.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the process can be used with a mixture of these components, which are not injectable, or a mixture of these components, which are not sterile.

Inventions II and III are related as process of making and process of using the product. The use as claimed cannot be practiced with a materially different product. Since the product is not allowable, restriction is proper between said method of making and method of using. The product claim will be examined along with the elected invention (MPEP § 806.05(i)).

This application contains claims directed to the following patentably distinct species: dosage form/ method of forming dosage form and method of treatment. For example with the dosage form/ method of forming dosage form there is the ablative agent (an osmotic-stress-generating agent) that could consist of one of various salts, i.e., sodium chloride or potassium chloride. In addition, the biodisintegrable binder is a component of the dosage form that in an effective amount provides the dosage form with suitable solid or semi-solid characteristics. Therefore, a wide range of these binding agent concentrations could be incorporated in the formulations in the said dosage form. These would vary greatly based on the characteristics of the ablative agent and other biodisintegrable agents included in said dosage form. In addition, one is drawn to a

method of treatment of said product. For example, one method of treatment is drawn to injecting the dosage form by jet injection (means of administering without the use of needles; a compression system) and another is drawn to a form of injection/insertion treatment consisting of a single needle and sample pusher (e.g., a mandrel or modified obturator).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Specifically, applicant is required to define. Currently, claims 1, 22, and 30 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims

Art Unit: 1614

readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should the applicant traverse on grounds that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is so. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Election/Restrictions Proper

MPEP §809.02(d) states “[w]here only generic claims are presented, no restriction can be required except in those applications where the generic claims recite such a multiplicity of species that an unduly extensive and burdensome search is necessary.” In this instant case, the claims cited are of such a multiplicity of species that an unduly extensive and burdensome search would be necessary if all of the claimed species were to be examined together.

The present claims are directed toward an injectable or insertable dosage form comprising a biodisintegrable binder and ablation agent in a concentration effective to cause tissue necrosis. Present claim 1 and claims dependent from claim 1 for example provide a variety of possibilities for the dosage form. It would present a serious search burden to the Examiner if all claimed species were searched together.

Further, as shown by the classifications, a majority of the combinations encompassed by the present claims has acquired a separate status in the art. For example, a particular dosage form containing an ablative agent and a biodisintegrable binder could have a myriad of combinations. For example, in the instant claims there

are numerous examples of both method of use and method of forming dosage form. Notwithstanding that the classification of some of the active ingredients (ablative

Art Unit: 1614

agent) and biodisintegrable binders are co-extensive, all of the claimed compositions are patently distinct and fully capable of supporting separate patents.

Rejoinder

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i). The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy E. Betton whose telephone number is (571) 272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER